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10/599,748	10/06/2006	Joseph R. Garlich	050990.0201.02USPC	3652
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EXAMINER				
ROYDS, LESLIE A				
ART UNIT		PAPER NUMBER		
1614				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,748

Applicant(s)

GARLICH ET AL.

Examiner

Leslie A. Royds

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 6, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 26Feb10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-14 are presented for examination.

Applicant's petition to revive the instant application after unintentional abandonment filed February 26, 2010 was received and entered into the present application. Pursuant to the decision mailed June 21, 2010, the petition was granted.

Applicant's Amendment and Information Disclosure Statement (IDS) filed February 26, 2010 have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references.

Claims 1-14 remain pending. Claims 1-4 and 7-12 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 5-6 and 13-14 are under examination.

Applicant's arguments, filed February 26, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claim 5 is objected to for failing to define the acronym "PTEN" at its first occurrence in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification as originally filed fails to provide adequate written description for "a pharmaceutically acceptable amount" of the claimed PTEN inhibitor, wherein R_1 is $\text{NHCOCH}_2\text{OPh}$ (claims 5 and 13).

Applicant discloses in the instant specification at para.[0037] that, "The term 'effective amount', when used in reference to a compound, product or composition as provided herein, means a sufficient amount of the compound, product or composition to provide the desired result. The exact amount required will vary depending on the particular compound, product or composition used, its mode of administration and the like. Thus, it is not always possible to specify an exact 'effective amount'. However, an appropriate effective amount may be determined by one of ordinary skill in the art informed by the instant disclosure using only routine experimentation."

Applicant provides a generic description of the "effective amount" of the claimed PTEN inhibitor compound to be administered, but has failed to provide any description of the particular amounts, or a range of amounts, that are either considered "effective amounts" or are considered "pharmaceutically acceptable amounts" as instantly claimed and would provide adequate written description of the claimed genus of amounts that are considered "pharmaceutically acceptable" as claimed that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the invention. In addition, it is unclear if Applicant intends for the terms "effective amount" and "pharmaceutically acceptable amount" to be synonymous. These facts coupled with the lack of guidance in the instant specification regarding the claimed "pharmaceutically acceptable amount" (aside from the guidance that an "effective amount" will be determined as appropriate for a desired therapeutic effect) fail

to provide clear written description of the metes and bounds of "pharmaceutically acceptable amounts" that are amenable for use in the context of the instant invention. Note, also, that the state of the art with regard to therapeutic uses of the instantly claimed PTEN inhibitor (i.e., the compound of instant claim 5, wherein R_1 is $\text{NHCOCH}_2\text{OPh}$ or the compound of instant claim 13) is not particularly well-developed such that the skilled artisan would have immediately envisaged the amounts that would be effective for the claimed purpose(s).

Applicant's instant specification fails to provide even an exemplary disclosure of dosage amounts that would be considered "pharmaceutically acceptable". Thus, the instant specification appears to lack any specific description of the amounts that would fall within the instantly claimed genus of pharmaceutically acceptable amounts such that these amounts could be immediately envisaged and/or readily identified. Absent such description, one of skill in the art would have to undertake extensive hit or miss testing to determine the full scope of the claimed genus of amounts, which is clearly indicative of the fact that Applicant was, in fact, *not* in possession of the full scope of amounts instantly claimed. This is because Applicant cannot logically be in possession of that which he has yet to identify.

Absent any clear description of even an exemplary amount that is considered "pharmaceutically acceptable" as instantly claimed, it remains that Applicant has failed to clearly define the metes and bounds of the claimed genus of amounts. While it is duly noted that the claimed genus is limited to those amounts that function in the claimed manner, it remains that Applicant has not appropriately defined the metes and bounds of the genus. The specification provides no disclosure beyond a generic disclosure that would correlate a particular amount to performance of a particular function that would be readily identifiable to one of skill in the art. Further, Applicant has failed to establish on the record that the state of the art was sufficiently well-developed that one of ordinary skill in the art at the time of the invention would have immediately envisaged the specific amounts that would meet the claimed function in the instant specification. In other words, the present specification provides no disclosure beyond the generic

disclosure of an “effective amount” *per se* that would provide a means for identifying the “pharmaceutically acceptable” amounts of the claimed compound that would have been amenable for use in the present invention, absent factual evidence to the contrary. Furthermore, it has been held that a wish or plan for obtaining the invention as claimed does not provide adequate written description of the invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties or a combination thereof (or, in the instant case, disclosure of at least an exemplary amount effective to provide function(s) claimed), is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for claim limitations must arise from either an explicit or implicit suggestion by the disclosure to show that such a concept as claimed was actually in possession of Applicant at the time of the invention. For the reasons provided *supra*, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of “a pharmaceutically acceptable amount” of the claimed PTEN inhibitor (claims 5 and 13).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Firstly, the phrase "treating damage to normal tissue attributable to heart disease" fails to clearly, precisely or deliberately set forth the therapeutic objective of the instantly claimed method recited in claims 5 and 13. In particular, it is unclear what "normal tissue" is both damaged and attributable to heart disease as instantly claimed. For example, it is unclear if the damaged tissue is heart tissue (damaged as a result of heart disease) or if it is any kind of tissue and, if so, whether it is "normal" or "abnormal" (i.e., damaged) tissue. Clarification is required.

Secondly, the phrase "in need thereof" as used to describe the patient subject to the instantly claimed method renders the claim indefinite because it is unclear if the patient is in need of the recited treatment (i.e., treatment of damage to normal tissue attributable to heart disease), in need of heart disease that causes the damage to normal tissue, or is in need of the recited step of administration (i.e., administration of the composition comprising a pharmaceutically acceptable amount of the recited PTEN inhibitor). As a result, the patient intended to be circumscribed by the instantly claimed method is not clearly set forth in the claims such that it would have been immediately apparent to one of skill in the art the type of patient to be treated. Clarification is required.

Thirdly, the phrase "pharmaceutically acceptable amount" renders the claim indefinite because it is not clear as to what parameters are necessary for the amount to be considered "pharmaceutically acceptable". For example, it is unclear as to whether the amount must not elicit an adverse or toxic effect upon administration in order to be considered "pharmaceutically acceptable" or whether the amount must elicit a particular therapeutic effect in order to be considered "pharmaceutically acceptable" as instantly claimed. Clarification is required.

Fourthly, and lastly, the antecedent basis of the term "a disease" in the phrase "a treatment for a disease suffered by the patient" as recited in instant claims 6 and 14 is not clearly set forth. It is unclear if Applicant intends for the term "a disease" to refer back to the "heart disease" that causes damage as recited in instant claims 5 and 13 or if it is intended to refer to any other coexisting condition of the patient to be treated. Clarification is required.

As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection. For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

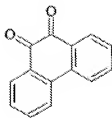
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Saxena et al. (WO 02/45702; 2002).

Saxena et al. teaches tricyclic compounds of formulas (I), (II), (III) or (IV), or a pharmaceutically acceptable salt thereof, for use in a medicament for the treatment of a chemokine mediated disease state (p.5, 1.9-p.6, 1.2), wherein an exemplary compound of the disclosed formulae is the compound 9,10-



phenanthrenequinone, which has the structure

(i.e., which corresponds to

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Applicant's compound of instant claim 5, wherein R_1 is hydrogen; p.15, l.15-22). Saxena et al. teaches that the compounds may be used for the treatment of various diseases, including, *inter alia*, atherosclerosis, inflammation, etc., and further teaches that atherosclerosis is a cardiovascular disease related to the accumulation of fatty streaks around arteries that are composed of lipid-laden macrophages and precede complex and dangerous lesions, as well as mediated by chemokines that modulate cellular entry into the vessel wall (p.2, l.25-32). Saxena et al. discloses that the compounds of the invention may be used in combination with other compositions for the treatment of diseases (p.20, l.16-18) and, further, that the active compound is administered in a therapeutically effective amount to achieve the desired therapeutic result (p.20, l.20-28).

Though the cited prior art of Saxena et al. is silent as to the claimed preamble objective of treating damage to normal tissue attributable to heart disease, it is noted that the teaching of an identical compound (or composition thereof) must necessarily possess the same functional property of treating damage to normal tissue attributable to heart disease in the subject of Saxena et al., even though such a property may not have been appreciated by the patentee at the time of the invention, because the patient treated in the prior art of Saxena et al. is identical to that instantly claimed (i.e., one in need of administration of the claimed PTEN inhibitor; note that the instant claims do not explicitly require the patient receiving the administration to be *in need of* treatment of damage to normal tissue attributable to heart disease, as discussed *supra*). This is because products of identical chemical composition cannot have mutually exclusive properties when used in the same manner because a chemical compound and its properties are inseparable. Thus, if the prior art teaches the apparently identical chemical structure for use in the same manner (or in the same host) as that instantly claimed, the properties Applicant discloses and/or claims must necessarily be present, absent factual evidence to the contrary.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or

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properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though the cited prior art may not expressly teach the claimed property of treating damage to normal tissue attributable to heart disease, the prior art clearly teaches the same step of administration of the same compound to the same host (i.e., a subject in need of administration of the claimed PTEN inhibitor) and, therefore, these resultant properties must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, the cited prior art does not possess these same claimed characteristics.

Conclusion

Rejection of claims 5-6 and 13-14 is proper.

Claims 1-4 and 7-12 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

August 20, 2010